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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,416	02/22/2002	Oliver Yoa-Pu Hu	39297-174170	8467

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EXAMINER

KIM, VICKIE Y

ART UNIT PAPER NUMBER

1614

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/079,416

Applicant(s)

YOA-PU HU ET AL.

Examiner

Vickie Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) 10-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election acknowledged

1. Applicant's election with traverse of Group I, claims 1-9, in Paper No. 5 is acknowledged. However, applicant fails to state the reason for his traversal. Thus, the traversal is not found persuasive, and the restriction requirement is maintained for the reasons of the record (Paper No. 4).

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

2. Claims 3-4 and 8-9 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The parent claims are drawn to a composition whereas the claims 4 and 8-9 are improperly further limiting the uses of the said composition. In this case, It fails to further limit the structure of the composition (structural changes). For instance, the recited limitations required by the claims 3-4 and 8-9 (i.e. anti-first-pass-effect, co-administered with a other compound, treatment for skin cancer) are describing the uses of the subject matter of the previous claim, but fail to further limit the structure of the composition. Thus, the subject matter (i.e. structures of the claim) is considered to be same as its previous claims. And thus,

Claim Rejections - 35 USC § 112

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1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 5-7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claim 5 recites the limitation "first-pass effect" in claim 1. There is insufficient antecedent basis for this limitation in the claim. Thus, claim 5 and its dependent claims 6-7 and 9 are properly included in this rejection.

- b. Claim 6 or 7 further recites the limitation "retinoid or retinoic acid"(respectively) as a specific species of the compound according to claim 1(claim 5 or claim 6 is ultimately dependent on claim 1). However, retinoid or retinoic acid is not found among the species recited in claim 1. There is insufficient antecedent basis for this limitation in the claim. Thus, claims 6-7 and its dependent claim 9 are properly included in this rejection.

3. Claims 3 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3 and 5 are rejected because the recited terms (i.e. compound with "anti-first-pass-effect" vs "first-pass effect") are not consistent. For instance, claim 3 recites that the compound(CYP1A) has anti-first-pass-effect whereas claim 5 recites that the compound has first-pass-effect. Therefore, the scope of the claims are indefinite because they are confusing. Therefore, clarification is required to obviate this rejection.

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4. Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-9 read on a dermal cytochrome P450 1A(CYP1A) inhibitor. However, the claims are indefinite because it is confusing whether the claims are drawn to a compound or a composition. The term "an inhibitor" is naturally characterized by its pharmaceutical features to show the said pharmacological effect(i.e.inhibiting activity). However, the limitation recited in the claim 1, "--- which is.....compound....", describe the inhibitor as being a compound not a composition. Therefore, this examiner is respectfully proposing replacement of the phrase "which is" in line 1 with the proper phrase such as "which comprises" or any equivalent terms to obviate this 112 rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1 , 3-6 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Burger et al (US 5,665,367).

Burger et al teach a dermal composition comprising quercetin and/or naringenin with retinoid (i.e. retinol or retinyl esters). Since this dermal composition taught in

cited reference meets all the critical elements required by the claims 1-9, the claimed subject matter is anticipated, see abstract and examples 1-10.

It is noted that cytochrome P450 1A inhibition is inherited feature wherein it is naturally occurring when the composition containing quercetin or naringenin is topically applied into the skin. One would have envisaged to have same inhibition when the dermal composition comprising quercetin and/or naringenin with retinoid is applied to treat dermal also envisaged to have same cytochrome P450 1A inhibitory activity. It is noted that claim 7 is properly included in this rejection regardless 112 rejection mentioned above, because retinoids(e.g. retinol or retinyl esters) are also taught by this reference.

5. Claims 1 , 3-6 and 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Burger et al (US 5,665,367).

Burger et al teach a skin care composition comprising retinoid(e.g. retinol), terpeneol and a vehicle, see claim 1. Instant claims 1-6, and 8-9 require a composition (dermal composition) containing terpeneol. All the critical elements required by the claims are taught by the cited reference and thus, the claims are anticipated. As mentioned earlier, CYP 1A inhibitory activity or anti-first-pass-effect is inherently possessed by the composition containing terpeneol as an active agent. It is noted that claim 7 is properly included in this rejection regardless 112 rejection mentioned above, because retinoids(e.g. retinol or retinyl esters) are also taught by this reference.

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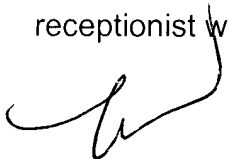
Conclusion

6. No claims are allowed.

7. Non-elected claims 10-16 are withdrawn from consideration.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675.

The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Vickie Kim,
Patent examiner
December 16, 2002
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